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In re Shigenori Ohkawa et al.	:	DECISION ON RECONSIDERATION
Application for Patent Term Extension	:	DISMISSING PETITION TO EXPUNGE
under 35 U.S.C. § 156	:	AND PLACING PROPRIETARY
Filed: September 7, 2005	:	INFORMATION UNDER
For: U.S. Patent No. 6,034,239	:	TEMPORARY ELECTRONIC SEAL

This is a decision on the patent owner's December 18, 2006 REQUEST FOR RECONSIDERATION. The patent owner asks that the Office reconsider the November 7, 2006 dismissal of its petition titled PETITION TO EXPUNGE CERTAIN PROPRIETARY INFORMATION FROM APPLICATION FOR EXTENSION OF PATENT TERM OF UNITED STATES PATENT NO. 6,034,239 UNDER 37 C.F.R. § 1.59.

The Request for Reconsideration is before the Office of Patent Legal Administration of the United States Patent and Trademark Office.

### SUMMARY

The decision of November 7, 2006 has been reconsidered in response to the patent owner's request, and is again dismissed. However, in view of the information provided in the Request for Reconsideration, Exhibit C has been placed under temporary electronic seal and is now unavailable to the public. The temporary seal will be lifted and the document again made available to the public unless the patent owner provides the Office with a revised Exhibit C that contains only the material from page 5 of Exhibit C as originally filed within the time period specified below.

### REVIEW OF FACTS

1. U.S. Patent No. 6,034,239 issued on March 7, 2000, based on application number 08/812,168 filed March 6, 1997.
2. On September 7, 2005, patent owner Takeda Pharmaceutical Company Ltd. filed an application with the U.S. Patent and Trademark Office (Office) for patent term extension (PTE) under 35 U.S.C. § 156.

3. Pursuant to 35 U.S.C. § 156(d)(2)(A)(ii), the Office forwarded a copy of the PTE application to the Food and Drug Administration (FDA) on October 11, 2005. The Office requested the FDA's assistance in determining that the identified product, ROZEREM™ (ramelteon), had been subject to the required regulatory review period, and that the PTE application had been filed within the statutory time period.
4. On February 24, 2006, the FDA replied to the Office, stating that the product had been subject to a regulatory review as required by 35 U.S.C. § 156(a)(4), and that the review had authorized the first permitted commercial marketing or use of the product under 35 U.S.C. § 156(f)(1). The FDA also verified that the PTE application had been timely filed.
5. On March 28, 2006, the Office informed the FDA that since the patent was considered to be eligible for patent term extension, it was necessary that the FDA determine the length of the applicable regulatory review period.
6. On June 19, 2006, the FDA published a Federal Register notice (71 Fed. Reg. 31275) regarding its determination of the regulatory review period. The period for requesting review of the FDA's determination expired on August 18, 2006. The period for petitioning for a determination of whether the applicant for PTE acted with due diligence before the FDA during regulatory review expired on December 18, 2006.
7. The patent owner filed a petition under 37 CFR 1.59 to expunge pages 1-4 and 6-38 of Exhibit C (all pages except page 5) on August 24, 2006.
8. On November 7, 2006, the Office issued a decision dismissing the patent owner's petition to expunge. The decision indicated that the patent owner could request reconsideration within two months of the date of the dismissal.
9. The patent owner's Request for Reconstitution was timely filed on December 18, 2006.
10. On January 10, 2007, the FDA forwarded a letter to the Office indicating that the determination of the regulatory review period had been finalized.

### **DECISION**

Section 2760 of the Manual of Patent Examining Procedure (MPEP) concerns trade secret, confidential, and protective order material filed in connection with an application for patent term extension under 35 U.S.C. 156, and states:

Proprietary or trade secret information [relating to an application for patent term extension] should be submitted generally in accordance with the

procedures set forth in MPEP § 724.02.

... If such information [submitted in accordance with MPEP § 724.02] was material to a determination of eligibility or any other Office responsibility under 35 U.S.C. 156, it will be made public at the time the certificate of extension is issued. Otherwise, if a suitable petition to expunge is filed before the issuance of the certificate, the trade secret or confidential information will be expunged from the file and returned to the patent term extension applicant.

Thus, MPEP 2760 invites a petition to expunge proprietary material in a 35 U.S.C. 156 patent term extension application when the proprietary material has been submitted in accordance with MPEP § 724.02; petitions to expunge generally are governed by 37 CFR 1.59(b). However, MPEP 2760 does not explicitly discuss procedures to be followed when, as has been alleged by the patent owner herein, proprietary materials are unintentionally submitted in a 35 U.S.C. 156 application for patent term extension. Furthermore, no other section of the MPEP has been identified that explicitly addresses this question. Therefore, in view of the recognized applicability of a petition to expunge in an application for patent term extension under 35 U.S.C. 156, at least in the particular circumstance of compliance with MPEP § 724.02, and in view of the lack of specific procedures for treating proprietary materials that were unintentionally submitted in an application for patent term extension under 35 U.S.C. 156, the procedure under MPEP 724.05 for treating a petition to expunge under 37 CFR 1.59(b) is followed in deciding the patent owner's petition, insofar as it may be adapted to the patent term extension context.

The patent owner acknowledges that the portion of the information in Exhibit C now stated to be proprietary information was not submitted in accordance with MPEP § 724.02.<sup>1</sup> Request for Reconsideration, page 1. Furthermore, the patent owner convincingly argues that subsections I and II of MPEP 724.05 are applicable to the present factual situation. Id. The patent owner then proceeds to provide an adequate explanation or assertion concerning requirements (A)-(E) of subsection I and requirements (A)-(F) of subsection II. Id. at 1-4.

Upon reconsideration and in view of the patent owner's explanations and assertions, Exhibit C has been electronically sealed, at least temporarily, and is presently not available to the public. Since the document in question is contained electronically in an Image File Wrapper (IFW), it cannot be physically returned to the patent owner. Rather, upon submission to the Office of a redacted version of Exhibit C containing only the material on page 5, the relief afforded to the patent owner will take the form of substitution of the redacted version for Exhibit C as originally filed, and the original Exhibit C will remain permanently electronically sealed.

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<sup>1</sup> MPEP § 724.02 requires that proprietary information be "filed in a sealed, clearly labelled, envelope or container."

The patent owner is reminded that proceedings concerning PTE applications are public; see MPEP 2753. Under current practice, when a PTE application is filed with the Office it is made publicly available via the public Patent Application Information Retrieval (PAIR) system. In PAIR, all patent prosecution and patent term extension documents are available to the public. Although the information which is the subject of this decision has now been at least temporarily electronically sealed, that information had already been made available to the public and had been subject to copying under 37 CFR 1.11(d), as indicated in the dismissal of December 7, 2006. Accordingly, the Office cannot guarantee that the materials currently under seal as a result of this decision were not previously accessed by the public.

For the foregoing reasons, the petition under 37 CFR 1.59(b) is dismissed.

The patent owner is given a period of **ONE MONTH** of the date of this letter to submit a redacted version of Exhibit C as discussed above. This period for response is non-extendable. If no reply to this decision is received within one month of the date of this letter, Exhibit C as originally filed will be unsealed and again available to the public, and this decision will become a final agency action within the meaning of 5 U.S.C. § 704.

### CONCLUSION

1. The November 7, 2006 decision dismissing the patent owner's petition of August 24, 2006 has been reconsidered as requested. The petition under 37 CFR 1.59(b) is again dismissed.
2. Exhibit C has been at least temporarily electronically sealed in view of explanations and assertions provided by the patent owner in the Request for Reconsideration of December 18, 2006.
3. The patent owner must provide a redacted version of Exhibit C to replace the original version within ONE MONTH of the date of this letter in order to avoid unsealing of original Exhibit C.
4. Telephone inquiries related to this decision should be directed to the undersigned at (571) 272-7754.



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